III. Legal Basis of Federal Quarantine Authority

The primary statutory authority to enact regulations for the purpose of communicable disease control is found at section 361 (42 U.S.C. § 264) of the Public Health Service Act. Section 361 is divided into four subsections. Subsection (a) authorizes the Secretary[1] to make and enforce such regulations "as in his judgment are necessary to prevent the introduction, transmission, and spread of communicable diseases" from foreign countries and from one state or possession into any other state or possession. Subsection (a) also authorizes a variety of public health measures, including destruction of articles determined to be sources of communicable disease. Subsection (b) authorizes the "apprehension, detention, or conditional release" of individuals to prevent the spread of communicable diseases as specified in Executive Orders of the President. Subsection (c) provides the basis for foreign quarantine of persons, while subsection (d) provides the basis for interstate quarantine of persons.

As prescribed in 42 U.S.C. § 271 and 18 U.S.C. §§ 3559 and 3571(c), criminal sanctions exist for violating regulations enacted under section 361. Specifically, individuals in violation of such regulations are subject to a fine of no more than $250,000 or one more year in jail, or both. Violations by organizations are currently subject to a fine no greater than $500,000 per event. Federal district courts also have jurisdiction to enjoin individuals and organizations from violating regulations implemented under section 361. See 28 U.S.C. 1331. Furthermore, section 311 (42 U.S.C. § 243) of the PHSA, authorizes the Secretary to accept state and local assistance in the enforcement of

[1] The Office of the Surgeon General was abolished by section 3 of the 1966 reorganization plan, effective June 25, 1966, 31 Fed. Reg. 8855. Accordingly, statutory references to the Surgeon General should be understood as referring to the Secretary.

quarantine regulations and to assist states and their political subdivisions in the control of communicable diseases.

Prevention of communicable diseases has long been the subject of federal regulation. In 1796, Congress enacted the first federal quarantine law in response to a yellow fever epidemic, which gave federal officials the authority to assist states in the enforcement of quarantine laws. In 1799, Congress repealed the 1796 Act and replaced with one establishing the first federal inspection system for maritime quarantines. In 1878, Congress amended the Quarantine Act to assign responsibilities to the Marine Hospital Service, which had been established in 1798 to provide for the health needs of merchant seaman. The 1878 Quarantine Act, however, was extremely limited and provided that federal quarantine regulations could not conflict with those of state or municipal authorities.

In 1893, Congress expanded the role of the Marine Hospital Service by enacting "An Act Granting Additional Quarantine Powers and Imposing Additional Duties upon the Marine Hospital Service." See Compagnie Francaise de Navigation a Vapeur v. State Board of Health, Louisiana, 186 U.S. 380, 395-96 (1902). While the 1893 Act did not abrogate the role of the states, it nonetheless granted the Secretary of the Treasury the authority to enact additional rules and regulations to prevent the introduction of diseases, both foreign and interstate, where state and municipal ordinances were deemed insufficient. Id. at 396. The Act also authorized direct federal enforcement of communicable disease regulations where state and municipal authorities refused to act. Id. Section 361 was enacted in 1944, and last amended in 2002.

Acknowledging the critical importance of protecting the public's health, long-standing court decisions uphold the ability of Congress and the States to enact quarantine and other public health laws, and to have them executed by public health officials. United States v. Shinnick, 219 F.Supp.789 E.D.N.Y. (1963). Kroplin v. Truax, 165 N.E. 498 (1929); Jacobson v. Massachusetts, 197 U.S. 11 (1905); North American Cold Storage Co. v. City of Chicago, 211 U.S. 306 (1908); Compagnie Francaise de Navigation a Vapeur v. Board of Health, 186 U.S. 380 (1902). Whereas the States derive public health authorities from the police power reserved to them by the 10th Amendment to the U.S. Constitution, the authority of the federal government to enact quarantine rules and regulations is based on the Commerce Clause, which grants to Congress the exclusive authority to regulate foreign and interstate commerce. See U.S. Const. Art. I, § 8, cl.3 (granting to Congress the power "to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.").

In addition to Congress' authority to regulate foreign commerce, the U.S. Supreme Court has identified three broad categories of interstate activity that Congress may regulate under its Commerce Clause authority: (1) the use of the channels of interstate commerce (e.g., prohibitions on the shipment in interstate commerce of noxious articles or kidnapped persons); (2) the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat to interstate commerce may come only from intrastate activities (e.g., regulations on railway rates); and (3) activities that substantially affect interstate commerce (e.g., labor standards). United States v. Lopez, 514 U.S. 549, 558-559 (1995). The proposed regulation is consistent with the scope of the federal government's commerce power because it seeks to regulate

the uses of the channels of foreign and interstate commerce (i.e., by protecting against the introduction, transmission, and spread of communicable diseases) and the instrumentalities of foreign and interstate commerce (e.g., airlines with flights arriving into the U.S. or traveling from one state or possession into another).

The proposed regulation also is consistent with the "search and seizure" requirements of the Fourth Amendment. Authority to "search and seize" in the form of inspections, detentions, and quarantine has long existed under the Public Health Service Act and the current regulations. The Fourth Amendment to the U.S. constitution provides that "[t]he right of the people to be secure in their persons, houses, papers, and effects, shall not be violated, and no warrants shall issue, but upon probable cause…." Courts have held, however, that not all types of searches and seizures necessarily require probable cause and a warrant. Searches and seizures conducted with the consent of an authorized person and those searches and seizures that are conducted to avert an imminent threat to health or safety do not run afoul of the Fourth Amendment even when conducted without probable cause and a warrant. See Lenz v. Winburn, 51 F.3d 1540, 1548 (11th Cir. 1995) ("Anyone who possesses common authority over or other sufficient relationship to the premises or effects sought to be inspected may consent to the search of another's property.") (internal quotations marks omitted); North American Cold Storage, 211 U.S. at 315 (upholding seizure of food unfit for human consumption). Similarly, individuals at points of entry and who are in transit have a substantially reduced expectation of privacy concerning their persons and effects and thus courts have not required that searches and seizures be conducted pursuant to probable cause and a warrant. See United States v. McDonald, 100 F.3d 1320, 1324-25 (7th Cir. 1996) (noting

that it is generally recognized that people who are in transit on common thoroughfares, i.e., on a bus, train, or airplane, have a substantially reduced expectation of privacy compared to persons in a fixed dwelling); United States v. Berisha, 925 F.2d 791, 795 (5th Cir. 1991) (noting that both incoming and outgoing border searches have features in common including the need to protect U.S. citizens, the likelihood of smuggling contraband, and the fact that individuals are placed on notice that their privacy may be invaded when they cross the border).

The U.S. Supreme Court has also recognized a reduced expectation of privacy concerning commercial industries that are "closely regulated" and thus searches and seizures of such commercial industries do not require probable cause and a warrant. See New York v. Burger, 482 U.S. 691, 702 (1987) (noting that the warrant and probable-cause requirements of the Fourth Amendment have lessened application in this context); Lesser v. Espy, 34 F.3d 1301, 1308 (1994) (upholding warrantless inspections of rabbit farms by the Animal Plant Health Inspection Program pursuant to the Animal Welfare Act). Specifically, warrantless inspections of "closely regulated" businesses are deemed reasonable provided that (1) there is a substantial government interest that informs the regulatory scheme pursuant to which the inspection is made; (2) the warrantless inspection is necessary to further the regulatory scheme; and (3) the inspection program, in terms of the certainty and regularity of its application, provides an adequate substitute for a warrant. Burger, 482 U.S. at 702-703.

Section 361(a) of the PHS Act (42 U.S.C. 264(a)) provides that regulations enacted by the Secretary may provide for inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or

contaminated to be sources of dangerous infection to human beings, and other measures that in the Secretary's judgment may be necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one state or possession into another. The statute also authorizes the apprehension, detention, and conditional release of persons reasonably believed to be infected with specified communicable diseases and arriving into the United States or traveling from one state into another. In carrying out this statutory authority, the proposed regulations authorize the Director to detain and inspect carriers and articles on board carriers for purposes of determining whether they may require the application of sanitary measures to prevent the introduction, transmission, or spread of communicable diseases.

The Director's delegated authority under section 361 is distinct from legal authority afforded to other federal agencies, such as USDA, which, among other things, includes the legal authority to prohibit or restrict the importation or entry of any animal, article, or means of conveyance, or the use of any means of conveyance or facility, if the USDA Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. See 7 U.S.C. 8303. In implementing measures necessary to prevent the introduction, transmission, and spread of communicable diseases that affect both human and livestock health, e.g., avian influenza, CDC would work collaboratively with USDA.

As previously noted, there are circumstances where courts have held that the Fourth Amendment does not require probable cause and a warrant, including searches conducted upon the consent of the individual and those necessary to avert an imminent

threat to human health or safety. Inspections conducted by quarantine officers at ports of entry and other locations will most often fall into one of these two categories. In addition, under the proposed regulations, the Director may compel inspections of carriers and the application of sanitary measures through written order. Furthermore, the proposed regulations provide the owners with an opportunity for a written appeal in the event that the Director orders the detention of a carrier or the destruction of animals, articles, or things, on board the carrier. Regarding individuals, the proposed regulation authorizes the provisional quarantine of persons arriving into the United States reasonably believed to be infected with or exposed to a quarantinable disease and persons who the Director reasonably believes to be in the qualifying stage of a quarantinable disease and traveling from one state into another or who are a probable source of infection to others who may be traveling from one state into another.

The routine inspection of persons or property for purposes of determining the presence of communicable disease is authorized by statute and does not fun afoul of the Fourth Amendment because of the reduced expectation of privacy inherent in travel and at border crossings. See United States v. Flores-Montano, 541 U.S. 149, 152 (2004) (noting that the Government's interest in preventing the entry of unwanted persons and effects is at its zenith at the international border and that border searches conducted pursuant to the longstanding right of the sovereign to protect itself by stopping and examining persons and property crossing into this country are reasonable simply by virtue of the fact that they occur at the border); McDonald, 100 F.3d at 1324 n.5 ("This diminished interest derives from, among other factors, the myriad legitimate safety concerns that pertain to those who travel by common carrier."). Air travel and shipping

are also closely regulated industries in the United States because these industries must comply with myriad regulatory requirements relating to safety, immigration, and homeland security. See United States v Dominguez-Prieto, 923 F.2d 464, 468 (6th Cir. 1991) (holding that common carriers in the trucking industry are pervasively regulated industries for purposes of warrantless inspections because of extensive federal and state regulations). Courts have also long recognized a substantial government interest in preventing the introduction, transmission, and spread of communicable diseases. See Jacobson, 197 U.S. at 11. Unsanitary carriers, as well as contaminated goods, may pose a threat to human health or safety, as well as lead to further contamination of other articles, if not immediately inspected and sanitized. The issuance of a written order by the Director, when necessary to compel compliance, accompanied by an opportunity for a written appeal, in the case of carriers ordered detained or animals, articles, or things ordered destroyed, also provides protections analogous to those of a warrant. See Burger, 482 U.S. at 711 (ruling that the administrative inspection program provided an adequate substitute for a warrant because it placed appropriate restraints on the discretion of the inspecting officers).

It is well recognized that freedom from physical restraint is a "liberty" interest protected by the Due Process Clause of the 14th Amendment to the U.S. Constitution. See Kansas v. Hendricks, 521 U.S. 346, 356 (1997) (noting that while freedom from physical restraint is at the core of the liberty protected by the Due Process Clause, that liberty interest is not absolute). In circumstances where due process is required, courts determine the process that is due by balancing the private interest affected by the official action against the government's asserted interest and the burdens that the government

would face in providing greater process. See Hamdi v. Rumsfeld, 124 S.Ct. 2633, 2646 (2004) (relying on Mathews v. Eldridge, 424 U.S. 319, 335 (1976)). Due process is a flexible concept requiring that the level of process granted be commensurate with the degree of deprivation and the circumstances of the event. See Parham v. J.R., 442 U.S. 584, 608 (1979) ("What process is constitutionally due cannot be divorced from the nature of the ultimate decision that is being made."). Furthermore, due process does not always require judicial-type hearings or quasi-criminal proceedings before curtailing an individual's physical liberty for public health purposes. See id. at 609 ("Although we acknowledge the fallibility of medical and psychiatric diagnosis, we do not accept the notion that the shortcomings of specialists can always be avoided by shifting the decision from a trained specialist using the traditional tools of medical science to an untrained judge or administrative hearing officer after a judicial-type hearing.") (internal citation omitted); Addington v. Texas, 441 U.S. 418, 431 (1979) (holding that states need not apply the strict criminal standard of proof beyond a reasonable doubt before committing the mentally ill); Morales v. Turman, 562 F.2d 993, 998 (5th Cir. 1977) (noting *in dicta* that "[a] state should not be required to provide the procedural safeguards of a criminal trial when imposing a quarantine to protect the public against a highly communicable disease."). The basic elements of due process include: reasonable and adequate notice of the action that the government is purporting to take (typically through a written order); an opportunity to be heard in a reasonable time and manner; access to legal counsel; and review of the government's actions by an impartial decision-maker. See Goldberg v. Kelly, 397 U.S. 254, 267-268 (1970) (discussing due process in the context of terminating welfare benefits). Because quarantine implicates an individual's liberty

interest to remain free from physical restraint, CDC in carrying out quarantine actions is obliged to act in a manner consistent with these basic elements of due process.

The proposed regulation establishes administrative procedures that afford individuals with due process commensurate with the degree of deprivation and the circumstances of controlling the spread of communicable disease. CDC quarantine officers are typically the first line of defense in preventing the importation of communicable diseases into the United States. Quarantine officers routinely conduct rapid assessments of ill passengers at airports and other ports of entry to assess the presence of communicable disease. Such assessments generally occur on a voluntary basis with the consent of the ill passenger. Where the quarantine officer reasonably believes that an ill passenger has a quarantinable disease, and the passenger is otherwise non-compliant, the quarantine officer may order the provisional quarantine of the passenger by serving the passenger with a written order, verbally ordering that the passenger be provisionally quarantined, or by ordering that actual restrictions be placed on a non-compliant passenger. The quarantine officer's reasonable belief would be informed by objective scientific evidence such as clinical criteria indicative of one of the specified quarantinable diseases, e.g., high fever, respiratory distress, and/or chills, accompanied by epidemiologic criteria such as travel to or from an affected area and/or contact with known cases. Provisionally quarantined individuals are provided with a written order in support of the agency's determination at the time that provisional quarantine commences or as soon thereafter as the circumstances reasonably permit. The written provisional quarantine order provides the individual with notice regarding the legal and scientific basis for their provisional quarantine, the location of detention, and

the suspected quarantinable disease. Under the proposed regulations, CDC may provisionally quarantine an individual for up to three business days unless the Director determines that the individual should be released or served with a quarantine order. CDC does not intend to provide individuals with administrative hearings during this initial three-day period of provisional quarantine, but rather will afford an opportunity for a full administrative hearing in the event that the individual or group of individuals is served with a quarantine order, which potentially would involve a longer period of detention.

While there are no federal cases establishing a specific time period for holding persons in quarantine-type detentions, there are several analogous federal cases dealing with "alimentary canal" smugglers, i.e., persons who smuggle drugs in their intestines by swallowing balloons. In United States v. Montoya de Hernandez, 473 U.S. 531 (1985), the U.S Supreme Court analogized holding a suspected alimentary canal smuggler to detaining someone for suspected tuberculosis, noting that "both are detained until their bodily processes dispel the suspicion that they will introduce a harmful agent into this country." Federal courts have upheld detention periods ranging from 16 hours to 20 days based on "reasonable suspicion" for suspected alimentary canal smugglers. CDC believes that the provisional quarantine of individuals for up to three business days without an administrative hearing is reasonable because such a time frame is necessary to determine whether the individual has one of the specified quarantinable diseases. A provisional quarantine order is likely to be premised on the need to investigate based on reasonable suspicion of exposure or infection, whereas a quarantine order is more likely to be premised on a medical determination that the individual actually has one of the quarantinable diseases. Thus, during this initial three business day period, there may be

very little for a hearing officer to review in terms of factual and scientific evidence of exposure or infection. Three business days may be necessary to collect medical samples, transport such samples to laboratories, and conduct diagnostic testing, all of which would help inform the Director's determination that the individual is infected with a quarantinable disease and that further quarantine is necessary. In addition, because provisional quarantine may last no more than three business days, allowing for a full hearing, with witnesses, almost guarantees that no decision on the provisional quarantine will actually be reached until after the provisional period has ended, thus making such a hearing virtually meaningless in terms of granting release from the provisional quarantine. In the event that further quarantine or isolation is necessary, the Director would issue an additional order based on scientific principles such as clinical manifestations, diagnostic or other medical tests, epidemiologic information, laboratory tests, physical examination, or other available evidence of exposure or infection. The length of quarantine or isolation would not exceed the period of incubation and communicability for the communicable disease as determined by the Director.

Under 28 U.S.C. § 2241, an opportunity for judicial review of the agency's decision exists via the filing of a petition for a writ of habeas corpus. This judicial review mechanism affords individuals under quarantine with the full panoply of due process rights typical of a court hearing. A petition for a writ of habeas corpus is the traditional mechanism by which individuals may contest their detention by the federal government. See Hamdi, 124 S.Ct. at 2644 (noting that absent suspension, the writ of habeas corpus remains available to all individuals detained within the United States); United States v. Shinnick, 219 F.Supp.789 (E.D.N.Y. 1963) (upholding the U.S. Public Health Service's

medical isolation of an arriving passenger because she had been in Stockholm, Sweden, a city declared by the World Health Organization to be a smallpox infected local area and could not show proof of vaccination).

In addition to this judicial review mechanism, as previously mentioned, the proposed regulations establish a procedure for individuals under quarantine to request an administrative hearing. The purpose of the administrative hearing is not to review any legal or constitutional issues that may exist, but rather only to review the factual and scientific evidence concerning the agency's decision, e.g., whether the individual has been exposed to or infected with a quarantinable disease. Such an administrative hearing would comport with the basic elements of due process. Under the proposed regulations, the Director would notice the hearing and designate a hearing officer to review the available evidence of exposure or infection and make findings as to whether the individual should be released or remain in quarantine. The proposed regulations authorize the Director to take such measures as the Director determines to be reasonably necessary to allow an individual in quarantine to communicate with their authorized representative to participate in the hearing.

In addition to section 361 of the PHS Act (42 USC 264), HHS also relies on the following legal authorities with respect to this notice of proposed rulemaking: 25 U.S.C. 198, 231, and 1661; 42 U.S.C. 243, 248, 249, 265-272, and 2001. 25 USC §§ 198, 231, 1661 and 42 USC 2001 contain legal authorities primarily relevant to public health measures taken with respect to Indian country. 42 USC §§ 265-272 contain legal authorities primary relevant to HHS operations and activities with respect to quarantine and other public health measures. These authorities are discussed in depth in Section IV.